The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

Paper No. 38

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte WALTER LANGE, MICHAEL GROSSE-BLEY, BRUNO BOMER, ROLF GROSSER, and FRANZ P. HOEVER

Appeal No. 1998-0900 Application No. 08/290,047

HEARD: April 5, 2001

Before WILLIAM F. SMITH, ROBINSON, and MILLS, <u>Administrative Patent Judges</u>. ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 - 4, 15, and 16. Claims 5 - 7 and 11 - 14 stand withdrawn from consideration by the examiner and are not presented on appeal.

Claim 1 is illustrative of the subject matter on appeal and reads as follows:

1. Polymerisable enantiomers of optically active dipeptides substantially free of other enantiomers, of the general formula (I)

in which

R¹ and R³ are identical or different and represent C₁-C₅-alkyl, A-O-CH₂, A-S-CH₂, CH₃-S-(CH₂)₂, cyclohexyl-CH₂, cyclohexyl, phenyl, benzyl, 4-A-O-benzyl, benzyl-CH₂, indolyl, naphthyl-CH₂ or naphthyl, where A is hydrogen, methyl, t-butyl or benzyl,

R² denotes hydrogen, methyl or fluorine,

X represents oxygen or NR⁵,

wherein R^5 is hydrogen, methyl, ethyl or, together with R^4 , forms a $C_5-C_6-[alkylidene]$ cycloalkyl radical, and

 R^4 represents a straight-chain or branched C_3-C_{18} -alkyl radical or a mono- to tetra- C_1-C_4 -alkyl-substituted C_3-C_{12} -cycloalkyl radical, benzyl, 1-phenylethyl or represents a phenyl which is mono- to disubstituted by fluorine, chlorine, trifluoromethyl, methoxy or C_1-C_4 -alkyl.

The references relied on by the examiner are:

Wagner et al. (Wagner)	3,850,646	Nov. 26, 1974
Heilmann et al. (Heilmann)	4,304,705	Dec. 08, 1981
Ishii et al. (Ishii)	4,396,706	Aug. 02, 1983

Takeshi Hibino et al. (Hibino)¹ 60-118,190 June 25, 1985 (Japanese Patent Application)

A reference cited by this merits panel:

Morrison and Boyd, <u>Organic Chemistry</u>, 2nd Ed., Allyn and Bacon, Inc., page 84, 1966. (Copy Attached)

Grounds of Rejection

Claims 1 - 4, 15, and 16 stand rejected under 35 U.S.C. § 112, first and second paragraphs, as being based on an insufficient written description and failing to particularly point out and distinctly claim the invention.

Claims 1 - 3 stand rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim that which applicants regard as their invention.

Claims 1 - 4, 15, and 16 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies on Hibino.

Claims 1 - 4, 15, and 16 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Wagner, Heilmann, and Ishii.

We affirm the rejection of claims 1 - 4, 15, and 16 under the first and second paragraph of 35 U.S.C. § 112, reverse the rejection under 35 U.S.C. § 112, second paragraph, alone, and reversed both rejections under 35 U.S.C. § 103. We,

¹ A translation of this Japanese Kokai Patent Application has been suppled to the PTO by The Ralph McElroy Translation Company in April 1996. While the examiner has listed the publication date of this reference as 8/1983 (Answer, page 5), we note that the publication date, according to the translation, is June 25, 1985 which is subsequent to the filing date of the application. Therefore, it does not appear that this document constitutes prior art to the presently claimed invention and we have not considered this document in resolving the issues presented by this appeal.

additionally, provide appellants with the opportunity to amend the appealed claims under the provision of 37 CFR § 1.196(c).

Discussion

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, and to the respective positions articulated by the appellants and the examiner. We make reference to the Examiner's Answer of June 11, 1996 (Paper No. 26) for the examiner's reasoning in support of the rejections and to the appellants' Appeal Brief filed March 4, 1996 (Paper No. 23) for the appellants' arguments thereagainst.²

Claim Interpretation

Claim 1 is directed to polymerisable enantiomers of optically active dipeptides defined by the following structure:

The

specifi

cation indicates the optically active polymers and copolymers can be obtained by

² The examiner has refused entry of the Reply Brief filed August 15, 1996 (Paper No. 29) and we have not considered it in our review of the issues raised by this appeal.

polymerization and copolymerization of these optically active dipeptides. For the purposes of this appeal, we find it unnecessary to determine whether claim 1 encompasses compositions or is directed, alternatively, only to the individual dipeptides defined by the structural formula. It is sufficient to note that claim 1 requires that what is claimed is "optically active." Thus, to the extent that the claim could be read to encompass a combination of more than one dipeptide optical isomer, it is clear that one isomeric form must predominate or there would be no observed optical activity. Thus, the claim can not be read to encompass a racemic mixture of dipeptides.

The rejections under 35 U.S.C. § 112

In rejecting claims 1 - 3 stand under 35 U.S.C. § 112, second paragraph, the examiner questions whether "[t]he phrase ' R^5 . . . together with R^4 , forms a C_6 - C_6 -cycloalkyl' is ambiguous. Does this mean that both R^5 and R^4 are individually cycloalkyl or they form a single cycloalkylidene moiety or they form a nitrogen heterocyclic moiety including the nitrogen to which they are attached?" (Answer, page 15). The examiner has given several examples of how one skilled in this art could presumably read the noted phase. (Id.) However, the examiner has not explained why the phrase, while capable of interpretation, should be regarded as unclear merely because it may be interpreted, alternatively, to encompass more than one possibility. In rejecting claim 3, the examiner urges that "it is not known what is intended by 'derived from'." The examiner urges that "[o]ne can derive a variety of different moieties from the same amino acid and it cannot be determined which derivative is being referred to in claim 3."

³ Morrison and Boyd, page 84 - "Clearly, if we are to observe optical activity, the material we are dealing with must contain an *excess* of one enantiomer; enough of an excess that the net optical rotation can be detected by the particular polarimeter at hand."

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(<u>Id.</u>) However, claim 3 depends from claim 1 and is directed to "[p]olymerisable optically active dipeptides according to claim 1, which are derived from" a defined group of amino acids. We read this claim to be directed to the optically active dipeptides of claim 1. Since the examiner does not find claim 1 indefinite in this regard, we do not agree that the use of product-by-process description as an alternative manner of claiming the subject matter would render claim 3 indefinite as to what is claimed.

It is well established that "definiteness of the language employed must be analyzed, not in a vacuum, but always in light of teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). The purpose of the second paragraph of Section 112 is to basically insure, with a reasonable degree of particularity, an adequate notification of the metes and bounds of what is being claimed. See In re Hammack, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970). Here, the examiner has failed to explain why the cited phrases result in claims 1 and 3 failing to meet the above standard. The examiner has the initial burden of demonstrating indefiniteness of the claims. In re

Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Thus, the examiner has not convincingly demonstrated that one of ordinary skill would not readily recognize the metes and bounds of the rejected claims. We, therefore, reverse the rejection of claims 1 - 3 under 35 U.S.C. § 112, second paragraph.

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Claims 1 - 4, 15, and 16 stand rejected under 35 U.S.C. § 112, first paragraph and second paragraph, as being based on a written description which does not support the presently claimed invention as to the use of the phrase "substantially free of other enantiomers" and are rendered indefinite by the terminology "substantially free."

(Answer, paragraph bridging pages 15-16). In rebuttal, appellants urge that the phrase "finds inherent support since the specification and claims specifically call for 'optically active'. If other enantiomers are present, they detract from the optical activity." (Brief, page 18). However, we do not agree that the phrase "optically active" would inherently suggest a product which was "substantially free of other enantiomers." Similarly, we are not persuaded that the melting points of the exemplified species (id.) can reasonably be read as providing a written description of this claim limitation. We agree with the examiner's position that the disclosure in support of the presently claimed invention lacks antecedent basis in the specification as filed for the phrase "substantially free of other enantiomers."

With respect to whether the claims are indefinite, we note that the disclosure presented in support of the claimed invention does not explicitly define what is meant by "substantially free." Further, appellants have not demonstrated that this phrase would have a meaning recognizable by one skilled in this art. Thus, it is not possible, without making unsupported assumptions, to interpret the phrase as meaning a pure optically active dipeptide. A product which is less than a racemic mixture would exhibit some level of optical activity. Without more, it is not readily apparent just what is

encompassed by the claim. Thus, the claims do not apprise those skilled in this art of the scope of the claimed invention, even when read in light of the specification. See In re Moore and In re Hammack, supra.

Thus, we find no error in the examiner's determination that the cited claim language lacks written descriptive support in the specification as filed and also renders the claims indefinite as to the scope of subject matter encompassed thereby.

Therefore, we affirm the rejection of claims 1 - 4, 15, and 16.

The rejections under 35 U.S.C. § 103

Claims 1 - 4, 15, and 16 stand rejected under 35 U.S.C. § 103 as being obvious over Hibino. Having determined that Hibino does not constitute prior art to the presently claimed invention, we reverse this rejection.

Claims 1 - 4, 15, and 16 stand rejected under 35 U.S.C. § 103 as obvious over the combination of Wagner, Heilmann, and Ishii.

The examiner relies on Wagner as disclosing "compounds that are homologous to the claimed compounds . . . [which] are used to prepare polymers." (Answer, page 10). The examiner relies on Heilmann and Ishii as establishing that "structurally similar compounds, homologous compounds do in fact possess a community of properties in common." (Id.). While the examiner has referenced column 12, lines 30-44 of Heilmann, the compound structurally represented, therein, is an acid rather than an ester as presently claimed and therefore lacks the alkyl group which is the

apparent focus of the homologous relationship between the claimed and prior art compounds.

From the statement of the rejection, as well as the discussion at pages 12-14 of the Examiner's Answer, which focuses on the compounds disclosed by Wagner, it is reasonable to conclude that the examiner regards the compounds of Wagner as being the most closely related to the claimed compounds. The examiner concludes that (Answer, page 11):

it would be obvious to one or ordinary skill in the art that homologous compounds having an alkyl substituent on the alpha carbon of the amino acid moieties would possess a community of properties in common. . . . Those of ordinary skill in the art [would] readily recognize that compounds having asymmetric carbon atoms possess optical isomers. (Citation omitted).

Appellants' principal argument as to whether the examiner has established a prima facie case of obviousness, focuses on the fact that none of the references mention optically active compounds or appreciate the importance of optical activity to the claimed invention. As stated above, the examiner has urged that the presence of an asymmetric carbon atoms in the prior art compounds would have suggested that the compounds exist as optical isomers. The examiner has, additionally, argued that "the claims have no requirement that is supported in the specification as to the purity of the claimed compounds and as such reads on any composition containing the recited compounds including mixtures of the compound with its optical isomers." (Answer, page 11).

The examiner does not offer an explanation as to how claim 1 directed to "Polymerisable enantiomers of optically active dipeptides" should be read as a composition which include mixtures of various optically active compounds. However, our reading of Wagner would suggest that this question is not relevant to the outcome of this aspect of the appeal.

Basic to the examiner's position is that one of ordinary skill in this art would recognize the presence of an asymmetric carbon as indicating the existence of optical active isomers of the prior art dipeptides. However, as appellants point out, the disclosed compounds of Wagner, on which the examiner relies (Answer, page 10), do not exhibit asymmetric carbons. Both carbons, which are asymmetric in the claimed compounds, are described as methylene (CH₂) by Wagner. (Brief, pages 4-5). Thus, there is nothing about this portion of Wagner which would suggest optically active isomers, and the examiner has provided no evidence which would reasonably suggest the modification of the dipeptides of Wagner in a manner to arrive at the claimed invention.

On this record, we find that the examiner has failed to provided evidence which would reasonably established that the claimed subject matter would have been <u>prima</u> <u>facie</u> obvious within the meaning of 35 U.S.C. § 103 at the time of the invention. The examiner's rejection of the claims is fatally defective since it does not properly account for and establish the obviousness of the subject matter as a whole. Where the examiner fails to establish a <u>prima facie</u> case, the rejection is improper and will be

overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). Therefore, we reversed the rejection of claims 1 - 4, 15, and 16 under 35 U.S.C. § 103 as unpatentable of the combined teachings of Wagner, Heilmann, and Ishii.

Having determined that the examiner failed to establish a <u>prima facie</u> case of obviousness within the meaning of 35 U.S.C. § 103, we found it unnecessary to consider the declarations submitted by appellants.

Statement under 37 CFR 1.196(c)

In affirming the rejection of the appealed claims under 35 U.S.C. § 112, first and second paragraph, we note that the phrase "substantially free of other enantiomers" did not appear in the original claims presented in this application, but was added by the amendment filed May 19, 1995 (Paper No. 16) to address the question of purity associated with rejections under 35 U.S.C. § 103. Further, we note the statement by appellants which indicate a willingness to delete "substantially free of other enantiomers" in order to avoid this rejection. (Brief, page 18). The cancellation of this phrase would avoid this rejection of the claims under 35 U.S.C. § 112. Therefore, under the provisions of 37 CFR § 1.196(c), we authorize the amendment of claim 1 consistent with appellants' proffer to remove the noted phrase.

Summary

The rejection of claims 1 - 4,15, and 16 under 35 U.S.C. § 112, first and second paragraphs, is affirmed. The rejection of claims 1 - 3 under 35 U.S.C. § 112, second paragraph, is reversed. The rejection of claims 1 - 4, 15, and 16 under 35 U.S.C. § 103

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over Hibino is reversed. The rejection of claims 1 - 4, 15, and 16 under 35 U.S.C. §

103 as unpatentable over the combination of Wagner, Heilmann, and Ishii is reversed.

This opinion includes a statement under 37 CFR § 1.196(c) authorizing the cancellation

of the phrase "substantially free of other enantiomers" which would overcome the

ground of rejection under 35 U.S.C. § 112, first and second paragraph.

Time Period for Response

A statement pursuant to 37 CFR § 1.196(c) has been made in this opinion. A

time period in which appellants may file an amendment for the purpose stated in

§ 1.196(c) in hereby set to expire TWO MONTHS FROM THE DATE OF THIS

DECISION.

No time period for taking any subsequent action in connection with this appeal

may be extended under 37 CFR § 1.136(a).

<u>AFFIRMED</u>; 37 CFR § 1.196(c)

William F. Smith

Administrative Patent Judge

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